Special Article

Pain Management and Prescription Monitoring

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Abstract

Preventing diversion and abuse of prescription controlled substances while ensuring their availability for legitimate medical use is an important public health goal in the United States. In one approach to preventing and identifying drug diversion, 17 states have implemented prescription monitoring programs (PMPs) to monitor the prescribing of certain controlled substances. While PMPs are not intended to interfere with legitimate prescribing, some in the pain management community feel that they negatively affect prescribing for pain management. This article describes a collaborative project initiated by the Pain & Policy Studies Group that brought together regulatory and pain management representatives twice in 1998 to share perspectives and reconcile differing views on the effects of PMPs. The ultimate goals of this project are to provide accurate information to healthcare clinicians about PMPs, better define the balance between preventing drug diversion and providing pain management, and promote continued dialog and cooperation among the groups. J Pain Symptom Manage 2002;23:231–238. © *U.S. Cancer Pain Relief Committee, 2002.*

Key Words

Prescription monitoring programs, triplicate prescriptions, single-copy serialized prescriptions, multiple copy prescriptions, electronic transmission, pain management, controlled substances, opioid analgesics, drug diversion, prescription drug abuse

Introduction

Undertreatment of pain is a major public health issue in the United States.[1–8] There are many safe and effective ways to treat pain. Drug therapy with opioid analgesics plays an important role in pain management and should be available when needed for the treatment of acute pain and chronic cancer, as well as non-cancer, pain.[6,9–14] Clinicians should be knowledgeable about using opioids to treat pain, and should not hesitate to prescribe them when opioids are the best clinical choice of treatment.[15] Because opioids have a potential for

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abuse, they are controlled substances under federal and state law.[16,17] Practitioners must know and comply with federal and state laws and regulations, and exercise sound professional judgement when prescribing opioid analgesics to minimize diversion and abuse of these drugs.

Prescription Controlled Substances, Drug Abuse, and Diversion

The diversion of prescription controlled substances to illicit channels is a public health and safety issue. These medications are diverted in numerous ways, including theft, forgery, and counterfeiting of prescriptions; illegal sales of prescriptions and drugs; fraudulent activities that victimize physicians, pharmacies, and patients; and by a small percentage of physicians who write prescriptions indiscriminately because they are dishonest, disabled, deceived, or dated in their practices.[18–20] Misuse and abuse of prescription controlled substances can and does lead to serious health consequences, including "drug dependence, overdose and deaths."[18] There is a need for additional studies to document the amount of opioid analgesics that is diverted from prescriptions, or compare this source of diversion with other sources, such as from pharmacy thefts.[4] The nature and extent of prescription drug abuse has been reported by the Drug Enforcement Administration (DEA),[21] and the abuse trends of opioid analgesics have been evaluated.[22]

The Role of Law and Government Agencies

There is no question that it is legal under federal and state law for duly licensed and registered physicians, pharmacists, and nurses to prescribe, dispense, and administer controlled substances for legitimate medical purposes and in the usual course of professional practice. Although all state laws are based on this premise, the provisions may differ from state to state. The National Conference of Commissioners on Uniform State Laws (NCCUSL) provides a model act to which states can refer.[17]

State and federal government agencies respond not only to the diversion and abuse of opioids and other controlled substances, but also to the treatment needs of patients, including those in pain. Regulatory agencies endeavor to ensure that the professionals who care for ill and injured persons are qualified to do so. State governments examine and license healthcare professionals and facilities. The DEA and some states issue controlled substances registrations to state licensed practitioners for prescribing, dispensing, and administering controlled substances. State and federal agencies enforce security and record-keeping to protect the manufacture and supply of opioid medications, while the federal government ensures their continued availability by setting production quotas that satisfy legitimate medical needs. Regulatory agencies also work to reduce drug abuse through substance prevention, treatment programs, and law enforcement. They also investigate and take appropriate action when there is evidence of illegal activity, practitioner impairment, or incompetence.

Evolution of State Prescription Monitoring Programs

It is within this broad context that a number of states have established prescription monitoring programs (PMPs). Table 1 describes the current status of PMPs in the United States. Typically, PMPs collect prescribing and dispensing data from pharmacies, conduct review and analysis of the data, and disseminate it to appropriate regulatory and law enforcement agencies. Following the lead of New York State in the 1910s, California and Hawaii enacted PMPs in the 1940s. By the 1980s, seven more states had added PMPs. These early programs required that physicians use multiple copy forms (duplicate or triplicate) to write prescriptions for Schedule II controlled substances, and that pharmacists send one copy to the state after dispensing a drug. Physicians were usually required to obtain prescription forms from a state agency, and some states charged a fee for the forms. After verifying the practitioner's credentials, the relevant state agency issued the requested forms.

In the 1990s, some states initiated PMPs that rely solely on computer technology to collect data. In these states, a special prescription form is not required. Pharmacies use electronic transmission to enter and transmit electronically to the state the PMP information about

Table 1
States With Prescription Monitoring Program

State	Year of Program Enactment	Program Type	Schedules/Drugs Covered	Initial Program Type	Year of Initial Program Enactment
California	1996	Triplicate/electronic	C-II	Triplicate	1939
Hawaii	1996	Duplicate Electronic	C-II C-II, III, IV	Duplicate	1943
Idaho	1997	Duplicate Electronic	C-II C-II, III, IV	Triplicate	1967
Illinois	1999	Electronic	C-II	Triplicate	1961
Indiana	1994	Single-copy/electronic	C-II, III, IV, V	Triplicate	1987
Kentucky	1998	Electronic	C-II, III, IV, V		
Massachusetts	1992	Electronic	C-II		
Michigan	1993	Single-copy, serialized/electronic	C-II	Triplicate	1988
Nevada	1995	Electronic	C-II, III, IV		
New Mexico	1994	Electronic	C-II		
New York	1998	Single-copy, serialized/electronic	C-II and benzodiazepines	Triplicate	1972
Oklahoma	1990	Electronic	C-II		
Rhode Island	1997	Electronic	C-II, III	Duplicate	1978
Texas	1997	Single-copy, serialized/electronic	C-II,	Triplicate	1981
Utah	1995	Electronic	C-II, III, IV, V		
Washington	1984	Triplicate	C-II, III, IV, V		
West Virginia	1995	Electronic	C-II		

Note: Current as of 10/30/00; prescription monitoring programs are subject to change.
Sources: Drug Enforcement Administration, "Prescription Accountability Resource Guide," September 1998; and updated information obtained from states.

controlled substances prescriptions that have been dispensed.

With the advent of recent technological advances, states that used multiple copy prescription forms have modified their PMPs to include an electronic element. In addition, most of these states replaced their multiple copy forms with a single-copy, serially numbered form (Hawaii and Idaho use duplicate prescription forms with electronic transmission, and California uses triplicate forms concurrently with its electronic transmission system). Rhode Island and Illinois are the only states to completely repeal the requirement to use a special prescription form; both states now use electronic transmission exclusively. A model prescription accountability act, recommended by the National Alliance for Model State Drug Laws and the National Association of State Controlled Substances Authorities (NASCSA), provides for a system that combines electronic monitoring and a serialized prescription form.[23]

In practice, PMPs take different forms because each state government determines the goals, structure, and organization of its program. Currently, the PMPs are administered by professional boards, health departments, human services agencies, or consumer protection agencies in 12 of the states; and by justice departments, public safety agencies, or state police in the other five states. The manner in which a program is implemented depends on its stated goals, the mission of the responsible agency, and rules regarding access to the data.

Purpose of PMPs

The purpose of PMPs is to reduce the diversion of prescription controlled substances. Objectives of PMPs usually include: 1) education and information; 2) public health initiatives; 3) early intervention and prevention of diversion; and 4) investigations and enforcement.[20] Prescription monitoring is not intended to interfere with medical practice[24] and attempts are made to make it minimally intrusive (e.g., reducing the paperwork burden by replacing multiple copy forms with single-copy serialized forms or eliminating forms altogether). PMPs do not require physicians to obtain prior approval to issue prescriptions, nor do they impose limits on the quantity that may be prescribed. Although some state laws limit quantities that can be prescribed in one prescription, such limits are established by laws other than those that establish PMPs.[25] Regulatory agencies that are charged with enforcing the laws with respect to

drug diversion also recognize the legitimate need for controlled substances in medical care.[26]

PMPs enable law enforcement investigators to obtain prescription information quickly and efficiently, thereby reducing time and resources that would be otherwise expended in obtaining the information from individual practitioners or pharmacies. PMPs can also provide an efficient means of handling complaints, and can result in speedier resolution of pending cases, dismissal of unfounded complaints, and avoidance of unnecessary investigations. Aggregate data on prescribing trends from most PMPs is usually available for educational and research purposes. In all uses of the data, confidentiality of prescribers, pharmacies, and patients is protected, thereby meeting another goal of PMPs.[20]

State agencies indicate that a PMP can have a deterrent effect on potential criminal activities. Early intervention in illegal activities is one of the identified goals of these programs. For example, state authorities report that use of special prescription forms significantly reduces or eliminates prescription forgery. In addition, PMPs are especially useful for identifying "doctor shopping," scams, and illicit prescribing and dispensing. Drug abusers who are identified as doctor shoppers can be directed into drug treatment or prosecuted, depending on the circumstances of the case. PMPs take into account the possibility that persons who seek pain medications may be patients with inadequately treated pain.[27]

Concerns about PMPs

Preventing drug diversion and abuse, and ensuring the availability of drugs for medical purposes are often perceived as potentially incompatible goals. For example, there has been considerable debate between regulatory and medical groups about the requirement for government-issued prescription forms. During the 1980s and 1990s, representatives of the medical community expressed concerns that these special forms were an intrusion into medical practice and the doctor–patient relationship. They were concerned about being investigated and about the additional administrative burden associated with handling a special form for this class of medication. Federal and state agencies charged with administering controlled substances laws responded that the programs were effective in reducing drug diversion,[15] with minimal impact on legitimate medical practice.[21,24,28]

A number of publications have examined the effect of multiple copy forms on diversion and medical practice.[29–38] The National Institute on Drug Abuse and the Institute of Medicine have called for more definitive research in this area.[33,39] States have worked with their medical communities to address their concerns. States, such as New York and Texas, which are replacing multiple copy prescription forms with an official single-copy prescription form and electronic transmission, assert that prescribing on a single-copy form rather than a multiple copy form is intended to be closer to the use of ordinary prescription forms. While single-copy forms reduce paperwork handling, they retain the ability to prevent prescription forgery and counterfeiting.[19]

Representatives of the Alliance of States with Prescription Monitoring Programs ("the Alliance"), the states with PMPs, and the DEA stress to physicians that prescription monitoring data cannot and do not serve as prima facie evidence of illicit activities. PMP data can provide an indication of a possible problem that may require further inquiry. Further, the PMP administrators stress that it is their intention that PMPs be used to enforce state laws in a manner that is most supportive of, and least disruptive to, medical and pharmacy practice.

Collaboration Between Pain Management and Regulatory Groups

In 1998, the University of Wisconsin Pain & Policy Studies Group (PPSG) initiated a collaborative project with the DEA, the Alliance, and the Analgesic Regulatory Affairs Committee of the American Pain Society (APS) in order to exchange perspectives on PMPs and the prescribing of opioids for pain management. The goal of the project was to explore how the groups could cooperate to ensure appropriate care for patients in pain, while protecting the public from diversion of opioids to non-medical, illicit use. The immediate objectives were to:

- enhance cooperation between the DEA, state PMPs, and the pain management community

- better define the balance between the provision of opioid analgesic treatment to patients in pain and prevention of diversion of opioids into non-medical, illicit use
- provide information on these issues to the professionals who care for patients and administer controlled substances laws.

Meetings

The PPSG organized two meetings to bring together individuals from these groups. The first meeting was held at the University of Wisconsin in Madison, Wisconsin, on 20–21 July 1998. Fifteen people were invited; thirteen were able to attend. (The representatives at the July 1998 meeting were: For the Alliance—Grant Carrow, Massachusetts Department of Public Health; John Eadie, State University of New York; David Hale, Oklahoma Bureau of Narcotics; Linda Schaefer, Texas Department of Public Safety. For the APS—June Dahl, APS Analgesic Regulatory Affairs Committee; Aaron Gilson, Pain & Policy Studies Group; David Haddox, American Academy of Pain Medicine; David Joranson, Pain & Policy Studies Group; David Mackey, Mayo Clinic Jacksonville; Karen Ryan, Pain & Policy Studies Group. For the DEA—Patricia Good, Office of Diversion Control; Susan Peine, Office of Diversion Control. Other—Thomas D. Wyatt, Jr., National Association of State Controlled Substances Authorities. Unable to attend were: William Marcus, California Deputy Attorney General; Russell Portenoy, Beth Israel Medical Center.) The meeting began with a discussion of the perspectives held by each of the attendees. Following the exchange, it was evident to participants that, although there were misconceptions regarding some issues, there was a shared interest in improving pain management and preventing the diversion of prescription controlled substances. The participants prepared a list of the points of agreement.

The initial points of agreement were refined at a second meeting, held in Charleston, South Carolina, on 29 October 1998 during the annual meeting of NASCSA. (The attendees for the October 1998 meeting were: Grant Carrow, Massachusetts Department of Public Health; John Eadie, State University of New York; Patricia Good, Drug Enforcement Administration; David Hale, Oklahoma Bureau of Narcotics; David Joranson, Pain & Policy Studies Group; Susan Peine, Drug Enforcement Administration; Karen Ryan, Pain & Policy Studies Group; Linda Schaefer, Texas Department of Public Safety; Thomas D. Wyatt, Jr., National Association of State Controlled Substances Authorities.) The nine participants at the second meeting decided to write a jointly authored article about the collaboration, and to consider future publications regarding PMPs.

The initial perspectives offered by the participants provided guidance for subsequent discussions. The group reached consensus on seven issues for which brief descriptions follow; where the consensus involved future action, the progress to date is noted.

Consensus

1. Publications

The participants felt that it is imperative to provide accurate information to educate the medical community about the purpose and operation of PMPs. A jointly authored article describing the collaboration will be prepared for publication in a medical journal. In addition, information about PMPs will be prepared by the Alliance for dissemination to physicians, pharmacists, nurses, and regulators. Both publications should describe the common goals of the prescription monitoring and pain communities.

Progress. This article is a result of the collaboration between the PPSG, the Alliance, the APS, and the DEA. In addition, the Alliance has prepared a document detailing the goals of prescription monitoring.[20] The DEA has compiled information from the states into two publications: "Prescription Accountability Resource Guide"[24] and "Committee Report on Establishing a State Prescription Monitoring Program."[28] The DEA and the National Alliance for Model State Drug Laws have compiled additional information from the states for another publication: "Diversion and Abuse of Prescription Drugs: A Closer Look at State Prescription Monitoring Programs."[21]

2. FSMB Guidelines

Many states have adopted pain policies in recent years. Twenty states have adopted the Federation of State Medical Boards (FSMB) "Model

Guidelines for the Use of Controlled Substances for the Treatment of Pain in whole or in part."[40] In many states, controlled substance, health, and law enforcement agencies have endorsed the Guidelines.

Progress. Representatives at the meeting supported the FSMB's Model Guidelines. They have also been endorsed by the DEA and NASCSA, as well as by the APS and the American Academy of Pain Medicine (AAPM).

3. Resource Information

The participants recommended that state and federal officials and the pain management community increase their efforts to exchange information. For example, they advised that pain specialists be available to PMPs to consult on interpretation of data. Regulatory agencies receive calls from patients whose physicians will not prescribe adequate pain medication for them. The pain management community could assist these patients by providing referrals to physicians with appropriate training in pain management. The Alliance can be used as a resource for the pain management community by providing contacts and information on PMPs in general, or on specific states.

Progress. General information on PMPs, including state and federal contacts, is available from the Alliance (http://www.nascsa.org/monitoring.htm), and the DEA Diversion Control Program (http://www.deadiversion.usdoj. gov/pubs/program/index.html). In addition, the Alliance and the DEA serve as clearinghouses for specific questions or issues concerning PMPs.

4. Reciprocal Meetings

The participants recommended that representatives from the pain management and regulatory and law enforcement communities present and participate in each others' meetings in order to provide information and to address questions and misperceptions. This kind of exchange can increase understanding of mutual goals, provide an opportunity to communicate about issues that arise, and address practitioners' concerns about regulatory oversight.

Progress. Representatives of the DEA, the Alliance, and the FSMB have been invited to participate in national and state pain meetings to clarify issues related to prescription controlled substances, PMPs, and medical boards' disciplinary responsibilities. State agencies routinely provide speakers for meetings of their state's medical associations and societies. These presentations have been greatly appreciated by clinicians. NASCSA has invited representatives from the pain field to make presentations at its annual meetings. The groups should continue these cooperative endeavors.

5. Scam Alerts

Information on the most recently identified "scams" should be included on the DEA's web page and in the APS Bulletin.

Progress. The DEA's website contains recent information on scams being used to procure prescription controlled substances illegally. It is available on the DEA web pages http://www.deadiversion.usdoj.gov/pubs/brochures/drugabuser.htm and http://www.deadiversion.usdoj.gov/pubs/pressrel/dr_scam.htm.

6. Federal Policy

Existing DEA policy recognizing the use of opioids for chronic pain should be disseminated more widely in the medical, pharmacy, and nursing communities.

Progress. The DEA regulations for prescribing and dispensing controlled substances are available on the following websites: DEA Diversion Control Program (http://www.deadiversion.usdoj.gov/21cfr/cfr/2106cfrt.htm), Government Printing Office (http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr1306_00.html), and by link from PPSG (http://www.medsch.wisc.edu/painpolicy). A DEA statement on the use of controlled substances for pain management is being drafted. It will be included in revisions of existing DEA publications about controlled substances for physicians,[15] pharmacists,[41] and nurses,[42] and will be included on its website: http://www.deadiversion.usdoj.gov/pubs/manuals/index.html. PPSG presentations generally include information about federal policy and informational resources.

7. Data

In keeping with state regulations, data from PMPs should be available to researchers to evaluate current trends in prescribing and the effectiveness of educational programs.

Progress. Data from prescription monitoring programs are available in the publications listed in item 1. Other projects that make use of PMP data, including university-sponsored research, are underway in various states. Educational facilities, pain management groups, and other specialty groups may find PMP data useful in evaluating treatment trends and the effectiveness of educational programs on pain management.

Conclusion

Representatives from pain management and prescription monitoring groups have recognized the importance of information exchange and cooperation. Since the meetings began in 1998, these groups have taken several important steps to increase cooperation and understanding and to nurture a mutual respect for the goals of each discipline. With continued activity expected in the states to improve pain management and address drug diversion, it is essential to continue these efforts to provide accurate information and promote communication and understanding between the groups involved.

Providing adequate pain management and preventing diversion and abuse of prescription controlled substances are both important public health goals. Achieving both goals requires exchange of information and perspectives, identification of issues, and concerted action. Increased communication and cooperation between regulatory and pain groups can contribute to a good balance between drug control and drug availability.

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